## TCT-730

### Numbers Needed to Treat Patients and Numbers Needed to Save Money. The Clinical and Economic Impact of TAVI and ICD face to face

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**Background:** Ageing, and the ever-increasing complexity of medical care requires an accurate assessment of the clinical advantages of treatments in relation to economic burden. A highly rated and conceptually simple indicator of this "weighed" intervention is the number needed to treat (NNT). Treating inoperable aortic stenosis patients with transcatheter aortic valve implantation (TAVI), as defined in the PARTNER trial, yields an NNT to save 1 life at 1 year of 5 (and 3.7 at 3 years). Such a formidable indicator of a "therapeutic-effort-to-clinical-yield" has never been so categorically proven in the most pivotal endpoint for interventional cardiology, and has led to a Class-I recommendation for TAVI in the recent European guidelines.
**Methods:** All European clinical and economic data used to calculate cost-benefit ratios was derived from publicly available data including peer-reviewed literature and national payment schedules (GHM for France, G-DRG for Germany, weighted National/Regional DRG tariffs and TAVI reimbursement.
**Results:** For the example of ICDs used in secondary prevention, it was estimated that the mean cost to the payer per death avoided at 1 year was €232,550, €197,098 and €244,335 for France, Germany and Italy respectively. For TAVI the corresponding cost per death avoided was €160,090, €150,872 and €122.007. In Italy this is also compounded by the recent introduction of medical device budget procurement caps.
**Conclusions:** The clinical data in support of TAVI is now strong and it is calculated that these impressive results are matched by the economic performance when comparing against other technologies which are often considered routine in their use. This argument extends beyond the single comparison of TAVI and ICDs, and we present here further analysis and examination of NNT as an appropriate measure of value driven benefits with medical devices.

## TCT-731

### TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) REDUCES SYMPATHETIC ACTIVITY AND NORMALIZES ARTERIAL SPONTANEOUS BAROREFLEX IN PATIENTS WITH AORTIC STENOSIS

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**Background:** TAVI is an emerging therapeutic option in pts with severe AS at high risk for open heart surgery.Whether pts with AS have increased sympathetic activity remains to be established and effects of TAVI on sympathetic nervous system is also unknown. We directly measured Muscle Sympathetic Nerve Activity (MSNA) in patients with aortic stenosis (AS) before and after transcatheter aortic valve implantation (TAVI) and compared MSNA with control patients.
**Methods:** we prospectively enrolled 14 patients with severe symptomatic AS treated by TAVI. Fourteen control patients matched for age, body mass index and unscathed of AS were also included. All patients underwent MSNA and arterial baroreflex gain (ABG) assessment at baseline and one week.
**Results:** Pts with AS had lower BP levels, significant increase in MSNA (61.0±1.7vs55.4±1.4 burst/min; $p<0.05$) and a decrease in ABG(2.13±0.14 vs 3.32±0.19 %burst/mmHg; $p<0.01$) compared to controls. TAVI induced an increase of BP associated with a significant decrease of MSNA (from 61.0±1.7 to 54.1±1.0 burst/min; $p<0.01$) and was associated with a significant increase of ABG (from 2.13±0.14 to 3.49±0.33 %burst/mmHg; $p<0.0$). One patient without sympathetic baroreflex improvement was the only one with moderate paravalvular aortic regurgitation (PAR).This could be interpreted as a result of pressure-induced change in afferent baroreceptor nerve activity thus leading to an increase of MSNA through a baroreflex-mediated mechanism.
**Conclusions:** We report for the first time, that pt with AS have elevated sympathetic nervous system (SNS) activity associated to a decrease in sympathetic baroreflex gain and that TAVI normalizes these parameters. This study provide evidences for a new beneficial effect of TAVI namely normalization of SNS hyperactivity. Additionally, knowing the deleterious effect of SNA in other cardiovascular diseases such as hypertension or CHF, the lack of normalization of SNS in the pt with moderate PAR could help to understand the relationship noticed between these significant regurgitations following TAVI and the worse survival associated, without any evidence of causality to date. However,this pathophysiological concept would need to be further evaluated.

## TCT-732

### Predictors of Aortic Arch Type: Implications in Patients with Severe Aortic Stenosis Being Evaluated for Transcatheter Aortic Valve Replacement

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**Background:** Type II and III aortic arches (T2-3AAs) are associated with lower procedural success and higher embolic complications in catheter based interventions. No definitive studies identify the cause of these challenging anatomical variations. We hypothesize the development of T2-3AAs is related to gravitational pull on the AA and brachiocephalic vessels by the heart over time therefore patients of advanced age and with increased left ventricular (LV) mass, such as those with severe aortic stenosis (AS) should have a higher incidence of T2-3AAs.
**Methods:** We reviewed 216 CT scans of the chest with contrast on patients that had a 2D echocardiogram done within 1 year. Of these patients 107 were found to have severe AS and evaluated for transcatheter aortic valve replacement (TAVR). AA type was determined by CT, then patient's baseline characteristics and echocardiographic parameters including, but not limited to LV ejection fraction (LVEF), LV mass, LV mass index, and relative wall thickness were analyzed. Complete data was available in 163 patients. The relationship between these variables and AA type was then tested in univariate and multivariate models.
**Results:** Univariate analysis revealed severe AS, increased age, weight, coronary artery disease, LV mass, and LV mass index and reduced LVEF were significantly correlated with type II and III AAs, however after multivariate analysis, only severe AS, increased age, and LVEF remained as independent predictors of AA type.

**Multivariate Model by Logistic Regression**

| Parameter | Odds Ratio | 95% Confidence Limits | Estimate | Standard Error | Wald Chi-Square | Pr > ChiSq |
|---|---|---|---|---|---|---|
| Severe AS | 4.197 | [1.6, 11.1] | 1.4344 | 0.4944 | 8.4165 | *0.0037* |
| Age (years)* | 1.49 | [1.1, 2] | 0.0399 | 0.0154 | 6.7363 | *0.0094* |
| LVEF (%)** | 1.37 | [1.0, 1.8] | -0.0314 | 0.0137 | 5.2349 | *0.0221* |

*continuous variable followed in 10 year intervals
**continuous variable followed in -10% intervals

**Conclusions:** Severe AS is the most powerful predictor of T2-3AAs. Advanced age and reduced LVEF also have a statistically significant independent correlation with T2-3AAs. This observation may explain the previously demonstrated benefit of the left subclavian approach in these patients and accordingly may merit further investigation into the adequacy and benefit of axillary access as smaller caliber TAVR delivery systems become available

## TCT-733

### Coronary Flow Reserve Pre and Post Transcatheter Aortic Valve Implantation in Severe Aortic Stenosis: An Invasive Evaluation Study of Coronary Flow Dynamics.

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**Background:** Transcatheter aortic valve implantation (TAVI) is an evolving management strategy for patients with aortic valve disease as an alternative to open aortic valve replacement. Patients with aortic stenosis (AS) have impaired coronary flow hemodynamics and this may partially explain the mechanism that causes angina in this condition. We sought to assess the effect of TAVI on coronary flow reserve (CFR), an established marker of coronary artery hemodynamic function.
**Methods:** We enrolled patients undergoing TAVI to have CFR invasively assessed immediately pre- and post-TAVI (at the time of their TAVI procedure) and again at 6 to 12 months. CFR was recorded as a ratio of average peak velocity, pre- and post-induction of maximal coronary microvascular hyperemia with administration of intracoronary adenosine. An intracoronary Doppler probe-tipped coronary flow wire was utilized for the CFR assessment.
**Results:** 10 patients were enrolled in the study with 8 having the follow-up evaluation performed. All patients had impaired CFR prior to TAVI (mean CFR 1.53, 95% CI 1.27 - 1.80). At follow-up invasive assessment there was a significant increase in CFR among the patients (mean % increase in CFR pre-TAVI to follow-up of 46.2%, 95% CI 16.1 – 76.3%, $p<0.01$) with a mean CFR of 2.18 (95% CI 1.88 – 2.47) at the follow up assessment. While there was a significant change from baseline pre-TAVI